

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0050]

Over-the-Counter Drug Products; Safety and Efficacy Review; Additional Dandruff Control Ingredient; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of eligibility; request for data and information; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to August 16, 2004, the comment period for the safety and effectiveness review of piroctone olamine, 0.05 percent to 0.5 percent and 0.1 percent to 1.0 percent, for use as a dandruff control single active ingredient in leave-on and rinse-off dosage forms, respectively. FDA published a notice of eligibility and call-for-data for safety and effectiveness data and information on piroctone olamine in the **Federal Register** of February 18, 2004. FDA is taking this action in response to a request for extension of the comment period to allow interested persons additional time to submit data and information on the safety and effectiveness of piroctone olamine as a dandruff control single active ingredient.

DATES: Submit data, information, and general comments by August 16, 2004.

ADDRESSES: Submit written comments, data, and information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments, data, and information to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Michael L. Koenig, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 18, 2004 (69 FR 7652), FDA published a notice of eligibility and call-for-data for safety and effectiveness information on piroctone olamine, 0.05 percent to 0.5 percent and 0.1 percent to 1.0 percent, for use as a dandruff control single active ingredient in leave-on and rinse-off dosage forms, respectively. FDA requested that all data, information, and general comments be submitted by May 18, 2004.

II. Extension of Time

On April 16, 2004, Keller and Heckman LLP, on behalf of Clariant GmbH, requested a 90-day extension beyond the May 18, 2004, deadline for the submission of safety and effectiveness data concerning piroctone olamine (Ref. 1). The request stated that additional time is needed to assemble a comprehensive submission for this ingredient. FDA considers an extension of time for submission of data, information, and general comments concerning the safety and effectiveness of piroctone olamine to be in the public interest. Accordingly, FDA is extending the comment period for 90 days to August 16, 2004, as requested.

III. Comments

Interested persons should submit comments, data, and general information to the Division of Dockets Management (see **ADDRESSES**) by August 16, 2004. Submit three copies of all comments, data, and information. Individuals submitting written information, or any individuals or entities submitting

electronic comments, may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by supporting information. Received submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Information submitted after the closing date will not be considered except by petition under 21 CFR 10.30.

IV. Marketing Policy

Under § 330.14(h), any product containing the conditions for which data and information are requested may not be marketed as an OTC drug in the United States at this time unless it is the subject of an approved new drug application or abbreviated new drug application.

V. Reference

The following reference is on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment No. EXT1.

Dated: May 12, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

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